K000392

DePuy
a Johnson & Johnson company

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:	DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
510(K) CONTACT:	Arlene C. Saull, RAC Sr. Regulatory Associate DePuy Orthopaedics, Inc. 700 Orthopaedic Drive Warsaw, IN 46581-0988
TRADE NAME:	Response™ 2000 Hip Stem
COMMON NAME:	Femoral Hip Prosthesis
CLASSIFICATION:	Class II, per 21 CFR, 888.3350
DEVICE PRODUCT CODE:	87 LZO Prosthesis, Hip, Semi-Constrained, Metal/Ceramic/Polymer, Cemented or Non-porous Uncemented.
SUBSTANTIALLY EQUIVALENT DEVICES:	DePuy Quantum Hip Stem DePuy Modular Press-Fit (MPF) Hip (Std. & MMA) DePuy Vision AML Hip Stems DePuy AML MMA Hip Stem

DEVICE DESCRIPTION:
The Response 2000 Hip Stem is manufactured from ASTM F-75 Co-Cr-Mo alloy. It is a smooth, straight-stem design, which will have a glass bead-blasted surface finish, a bullet-shaped distal tip, and is designed with a self-locking taper for use with a DePuy femoral head.

INDICATIONS AND INTENDED USE:

Intended Use:
The Response 2000 Hip Stem is intended for press-fit or cemented use in total hip arthroplasties.

Indications:
Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.

2. Avascular necrosis of the femoral head.

3. Acute traumatic fracture of the femoral head or neck

4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.

5. Certain cases of ankylosis.

Non Porous-Coated Press-Fit or Cemented Components:
Non Porous-coated femoral hip stem prostheses labeled "FOR PRESS-FIT OR CEMENTED USE" are indicated for press-fit uncemented use, or for use with bone cement.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The subject devices are identical to the predicate hip stem devices, in that they have the same straight stem geometry, materials and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 4 2000

Ms. Arlene C. Saull, RAC
Senior Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K000392
Trade Name: Response 2000 Hip Stem
Regulatory Class: II
Product Code: LZO and JDI
Dated: February 4, 2000
Received: February 7, 2000

Dear Ms. Saull:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS

510(k) Premarket Notification

510(k) Number (if known) K000392

Device Name Response™ 2000 Hip System

Note: *(The package insert includes intended use/indications for several types of femoral components. The below text, which is extrapolated from the package insert (see Exhibit D), contains only the intended use/indications pertinent to the Response 2000 Hip Stem.)*

Indications for Use:

Total hip arthroplasty is intended to provide increased patient mobility and reduce pain by replacing the damaged hip joint articulation in patients where there is evidence of sufficient sound bone to seat and support the components. Total hip replacement is indicated in the following conditions:

1. A severely painful and/or disabled joint from osteoarthritis, traumatic arthritis, rheumatoid arthritis, or congenital hip dysplasia.
2. Avascular necrosis of the femoral head.
3. Acute traumatic fracture of the femoral head or neck.
4. Failed previous hip surgery including joint reconstruction, internal fixation, arthrodesis, hemiarthroplasty, surface replacement arthroplasty, or total hip replacement.
5. Certain cases of ankylosis.

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Concurrence of CDRH, Office of Device Evaluation:

Donna R Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K000392

Prescription Use X OR Over-The Counter Use ___(Per 21 CFR 801.109)